IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., ASTRAZENECA AB, SHIONOGI SEIYAKU KABUSHIKI KAISHA, and THE BRIGHAM AND WOMEN'S HOSPITAL, INC.,	)	
Plaintiffs,	)	C.A. No. 10-915-LPS
v.	)	**PUBLIC VERSION OF D.I. 64**
WATSON LABORATORIES, INC. (NV),	)	
Defendant.	)	

CORRECTED MEMORANDUM IN SUPPORT OF DEFENDANT WATSON LABORATORIES, INC. (NV)'S MOTION TO DISMISS

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STATUTES & RULES

Defendant Watson Laboratories, Inc. (NV) ("Watson") moves the Court pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6) for an order dismissing Counts II and III of the Amended Complaint filed by Plaintiffs AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., AstraZeneca AB, Shionogi Seiyaku Kabushiki Kaisha, and The Brigham and Women's Hospital, Inc. ("Plaintiffs").

I. INTRODUCTION

Last year in this Court, Plaintiffs asserted against several generic drug companies, including two Watson subsidiaries, the same method-of-use patents asserted here against Watson in newly-added Counts II and III of Plaintiffs' Amended Complaint. As in the present Amended Complaint, Plaintiffs alleged in the prior case that the defendants' FDA applications were artificial acts of infringement under Section 271(e)(2) of the Hatch-Waxman Act, [redacted] This Court dismissed Plaintiffs' previous claims, correctly holding that Section 271(e)(2) cannot confer jurisdiction where the FDA applicant is not seeking approval for the claimed methods of use.

The same operative facts that justified dismissal in the previous case exist in the present case, and likewise warrant dismissal of Counts II and III in Plaintiffs' Amended Complaint. [redacted] Thus, the Court should dismiss Counts II and III.

Policy considerations also support dismissal. The Hatch-Waxman Act, in an effort to speed application approval and appropriate market entry, [redacted]

[redacted] Plaintiffs once again try to undermine that policy by attempting to create a new and unjustified cause of action under Section 271(e)(2). The Court, as it has already done before, should reject Plaintiffs' misguided attempts and dismiss Counts II and III of Plaintiffs' Amended Complaint.

II. BACKGROUND AND FACTS

Counts II and III of the Amended Complaint purport to be claims under the Hatch-Waxman Act, arising from Watson's submission of NDA No. 202172, which seeks approval to market rosuvastatin *zinc* tablets — a novel salt form of the rosuvastatin active ingredient. Plaintiffs market rosuvastatin *calcium* tablets under the trade name CRESTOR®.

Because Watson seeks approval for a novel salt form, it submitted its application as a New Drug Application ("NDA") under Section 505(b)(2), rather than as an Abbreviated New Drug Application ("ANDA"), but both applications are treated the same for purposes of Hatch-Waxman litigation. 21 U.S.C. §§ 355(b)(2), (j). An NDA under Section 505(b)(2) is sometimes referred to as a "Paper NDA."

The patents asserted in Counts II and III are U.S. Patent Nos. 6,858,618 ("the '618 patent") and 7,030,152 ("the '152 patent"). Neither patent claims the drug rosuvastatin or a particular formulation of rosuvastatin. Instead, each is directed to particular methods of treating particular medical conditions. The '618 patent claims methods of treating heterozygous familial hypercholesterolemia ("HeFH"). (D.I. 48, Am. Compl. Ex. A, '618 patent, at Abstract). The '152 patent claims methods of treating "a nonhypercholesterolemic human" in order to "reduce the risk of a cardiovascular disorder." (D.I. 48, Am. Compl. Ex. E, '152 Patent, at 32:7–17). CRESTOR® is approved for indications allegedly relating to these uses.

[redacted]

Plaintiffs fail to allege that Watson has sought or is seeking FDA approval of its rosuvastatin zinc product for the indications relating to the uses claimed in the '618 and '152 patents, or for any other method of use allegedly claimed by these asserted patents. Plaintiffs include only an unsupported, conclusory allegation that Watson should have filed a Paragraph IV certification regarding these asserted patents.

This is not the first time Plaintiffs have asserted in this Court the '618 and '152 patents [redacted] Plaintiffs last year, weeks after trial involving the rosuvastatin compound patent, sued Watson subsidiaries Cobalt Pharmaceuticals, Inc. and Cobalt Laboratories, Inc., along with several other defendant generic drug companies, in this Court for infringement under Section 271(e)(2) based on the '618 and '152 patents ("Rosuvastatin Calcium II"). *AstraZeneca Pharms. LP v. Apotex Corp.*, No. 10-338, 2010 U.S. Dist. LEXIS 132727 (D. Del. Dec. 15, 2010). The '618 and '152 patents expire well after the rosuvastatin compound patent. [redacted] the

[1] [redacted] *AstraZeneca Pharms. LP v. Apotex Corp.*, No. 10-338, 2010 U.S. Dist. LEXIS 132727, at *30–31 (D. Del. Dec. 15, 2010).

defendants had certified to the FDA that they were not seeking approval for the claimed methods, and had carved out from their proposed indications any methods of use purportedly covered by the '618 and '152 patents.[2] *Id.* at *14-20. Judge Kugler, sitting by designation in this Court, dismissed Plaintiffs' Section 271(e)(2) claims for lack of subject matter jurisdiction because the defendants' product labels did not actually seek approval for the patented indications, nor were they required by the FDA to include such indications. *Id.* at *45. That decision is currently on appeal to the Federal Circuit. [redacted]

III. ARGUMENT

A. Legal Standards For Dismissal Under Rules 12(b)(1) And 12(b)(6)

The Court is familiar with the legal standards applied to challenges to subject matter jurisdiction under Rule 12(b)(1), and applied to motions under Rule 12(b)(6) for failure to state a claim. In a factual challenge under Rule 12(b)(1), the Court may consider evidence outside the pleadings. *AstraZeneca*, 2010 U.S. Dist. LEXIS 132727, at *25-26. The Court has the power to weigh the evidence and determine subject matter jurisdiction. *Id.* The burden of establishing jurisdiction in a factual challenge is on the plaintiff. *Id.*

The Court's power to adjudicate a case rests upon the existence of a "case [or] controversy" that is ripe for judicial intervention. *Wyatt v. Gov't of the Virgin Islands*, 385 F.3d 801, 806 (3d Cir. 2004). As explained by the Third Circuit, "[t]he purpose of the ripeness

[2] Since the defendants in Rosuvastatin Calcium II were seeking approval to market generic versions of rosuvastatin calcium rather than a novel rosuvastatin salt form [redacted] the previous case involved ANDAs rather than Paper NDAs. [redacted]

doctrine is to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Id.* (internal quotations and citations omitted).

Whether a dispute has matured sufficiently to permit adjudication depends on (1) "the fitness of the issues for judicial decision" and (2) "the hardship to the parties of withholding court consideration." *Id.* Under the fitness inquiry, the Court should consider factors, such as whether the claim involves uncertain and contingent events that may not occur as anticipated or at all. *Philadelphia Fed'n of Teachers v. Ridge*, 150 F.3d 319, 323 (3d Cir. 1998). Under the hardship inquiry, the Court must consider whether the challenged action "creates a 'direct and immediate' dilemma for the parties, such that the lack of pre-enforcement review will put the plaintiffs to costly choices." *Id.* (citing *Abbott Labs. v. Gardner,* 387 U.S. 136, 152 (1967); *W.R. Grace & Co. v. United States EPA*, 959 F.2d 360, 364 (1st Cir. 1992)). "Claims based merely upon 'assumed potential invasions' of rights are not enough to warrant judicial intervention." *Wyatt*, 385 F.3d at 806 (quoting *Ashwander v. Tennessee Valley Auth.*, 297 U.S. 288, 324–25 (1936)). Thus, a case is not ripe for adjudication and must be dismissed under Rule 12(b)(1) "if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas v. United States*, 523 U.S. 296, 300 (1998) (internal quotations and citations omitted).

In ruling on a motion to dismiss under Rule 12(b)(6), "[t]he standard is the same when considering a facial attack under Rule 12(b)(1) or a motion to dismiss for failure to state a claim under Rule 12(b)(6)." *Petruska v. Gannon Univ.*, 462 F.3d 294, 299 n.1 (3d Cir. 2006). A court

reviewing a motion to dismiss under Rule 12(b)(6) must "accept the complaint's allegations as true, [and] read those allegations in the light most favorable to the plaintiff." *Umland v. Planco Fin. Servs., Inc.*, 542 F.3d 59, 64 (3d Cir. 2008). The complaint must be dismissed if it does not allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is plausible only if "the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009). The plausibility standard requires more than a "sheer possibility that a defendant has acted unlawfully." *Id.* Rather, the "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555 (citation omitted).

Under either Rule 12(b)(1) or Rule 12(b)(6), a court may consider, in addition to the allegations in the complaint, "documents that are attached to or submitted with the complaint . . . and any matters incorporated by reference or integral to the claim, items subject to judicial notice, matters of public record, orders, [and] items appearing in the record of the case." *Buck v. Hampton Twp. Sch. Dist.*, 452 F.3d 256, 260 (3d Cir. 2006) (internal quotations and citation omitted); *see also City of Pittsburgh v. West Penn Power Comp.*, 147 F.3d 256, 259 (3d Cir. 1998) (holding that public records relating to relevant regulatory proceedings may be used by the Court in forming its decision when evaluating a motion to dismiss); *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1197 (3d Cir. 1993) (holding that public records, including letter decisions of government agencies, may be considered on a motion to dismiss). The Court may consider documents that are "integral to or explicitly relied upon in the complaint," even if not attached to the complaint, "without converting the motion to dismiss into

one for summary judgment." *Angstadt v. Midd-West Sch. Dist.*, 377 F.3d 338, 342 (3d Cir. 2004) (internal quotations and citations omitted).

B. Counts II And III Are No Different From Plaintiffs' Previously-Rejected Attempts To Assert The '618 And '152 Patents, And Should Be Dismissed For The Same Reasons

No material difference exists between Counts II and III in this case and the Section 271(e)(2) claims that were dismissed in Rosuvastatin Calcium II. The Court should therefore dismiss Counts II and III for the same reasons it dismissed Plaintiffs' Section 271(e)(2) claims in the previous case.

The Court held in Rosuvastatin Calcium II that no justiciable case or controversy under Section 271(e)(2) exists where a drug company is not seeking approval for the use allegedly claimed in the patent. *AstraZeneca*, 2010 U.S. Dist. LEXIS 132727, at *3. In so holding, the Court noted that infringement under Section 271(e)(2) is not only artificial, but limited, *i.e.*, it was not intended to provide patentees with an opportunity to assert all patents that conceivably relate to the composition or use of a branded drug. *See id.* at *41-42. The Court emphasized that Congress enacted Section 271(e)(2) with the expectation that drug companies could carve out FDA-approved, patented uses, and that such carve outs would remove any justiciable case or controversy under Section 271(e)(2). *Id.* at *39-40.

Turning to the merits, the Court concluded in Rosuvastatin Calcium II that defendants were not seeking approval for the methods claimed in the '618 and '152 patents, and dismissed Plaintiffs' Section 271(e)(2) claims, noting that: (1) defendants had filed Section viii Statements, certifying that they were not seeking approval for any indications claimed in the '618 and '152 patents, (2) defendants' proposed labeling excluded these patented indications, and (3) Plaintiffs

failed to allege that defendants were seeking approval for the indications claimed in the '618 and '152 patents. *Id.* at *13-20, *38-45.

It is important to note that while the Court dismissed Plaintiffs' claims for lack of subject matter jurisdiction, the Court's reasoning equally supported dismissal under Rule 12(b)(6) for failure to state a claim even though the Court did not reach the merits of that issue. *Id.* at *24-25, *34-35 (explaining that jurisdiction under Section 271(e)(2) turns on whether a plaintiff asserts a valid 271(e)(2) claim).

[redacted] Indeed, Plaintiffs have not even alleged that Watson is seeking approval for any indication allegedly covered by the '618 or '152 patents. Plaintiffs' failure to do so is telling given the Court's previous admonishment about not including such an allegation. *Id.* at *22-23 n.9 ("If Plaintiffs believe that Defendants' proposed labeling includes patented indications, they must specifically allege that fact."). [redacted] The Court should therefore dismiss Counts II and III under Rule 12(b)(1) for lack of subject matter jurisdiction, or under Rule 12(b)(6) for failure to state a claim.[3]

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[3] [redacted] *See Bayer Schera Pharma AG v. Sandoz, Inc.*, 741 F. Supp. 2d 541, 551 (S.D.N.Y. 2010) ("FDA regulations explicitly provide that other uses and indications not listed in the 'Indications and Usage' section of the label may not be implied based on other sections of the label . . . .") (citing 21 C.F.R.

Policy considerations also dictate that Plaintiffs cannot stretch the limited Section 271(e)(2) framework beyond the boundaries Congress intended. According to the Federal Circuit, Section 271(e)(2) is not the proper statutory vehicle for Plaintiffs' infringement allegations:

> [Infringement under Section 271(e)(2) is] limited to an analysis of whether what the generic drug maker is requesting authorization for in the ANDA would be an act of infringement if performed . . . . That a generic maker may someday induce someone to infringe can only be determined when that act occurs, and § 271(e)(2) was not designed to cover such future acts.

Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1364–65 (Fed. Cir. 2003).

By asserting Section 271(e)(2) claims based on the '618 and '152 patents, Plaintiffs are attempting to create a new cause of action under the Hatch-Waxman framework to improperly delay approval of Watson's NDA. The Court should deny Plaintiffs' improper attempt to circumvent Congress's clear structure governing Hatch-Waxman litigation.

C. <u>An Act Of Patent Infringement Under Section 271(e)(2) Cannot Be Committed Without A Paragraph IV Certification To That Patent</u>

Plaintiffs attempt to allege infringement of the '618 and '152 patents under Section 271(e)(2) [redacted] In so doing, Plaintiffs insist that the Court should simply ignore the substantive rights of Paper NDA and ANDA filers, and the narrow, particularized litigation path that Congress established in the Hatch-Waxman Act.

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§ 201.57(c)(2)(iv)). [redacted]

1. The Substantive Rights Of ANDA And Paper NDA Filers And The Particularized Litigation Path Established By The Hatch-Waxman Act

As part of an ANDA or Paper NDA, the applicant must make a certification as to each patent that is listed in the Orange Book that "claims the listed drug . . . or which claims a use for such listed drug *for which the applicant is seeking approval.*" 21 U.S.C. § 355(j)(2)(A)(vii); *see also* 21 U.S.C. § 355(b)(2)(A) (emphasis added). The four certifications are commonly referred to by the corresponding paragraph number in the statute that describes them, *i.e.*, Paragraphs I through IV.

- A "Paragraph I" certification represents to the FDA that no patents claiming the drug product or its use for which the filer seeks FDA approval have been submitted for listing in the Orange Book;
- A "Paragraph II" certification represents to the FDA that a patent claiming the drug product or its use for which the filer seeks FDA approval has expired;
- A "Paragraph III" certification represents to the FDA that the ANDA filer is not requesting approval to market its product until the patents that claim the drug product or its use expires; and
- A "Paragraph IV" certification represents to the FDA that the ANDA filer believes that a patent claiming the drug product or its use is invalid or will not be infringed by the ANDA product.

21 U.S.C. §§ 355(j)(2)(A)(vii)(I)–(IV).

When the Orange Book lists a patent that claims a method of using a drug, the Paper NDA or ANDA applicant may tell the FDA that it is not seeking approval for the patented method of use. 21 U.S.C. §§ 355(b)(2)(B), (j)(2)(A)(viii); *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 880 (D.C. Cir. 2004). If the applicant elects not to request FDA approval of that claimed method of use, the applicant may submit in the Paper NDA context a "Section 505(b)(2)(B) Statement," or in the ANDA context a "Section viii Statement," declaring that the applicant does not seek approval for the use claimed by the patent. 21 U.S.C. §§ 355(b)(2)(B), (j)(2)(A)(viii).

Along with the certification, the applicant "must submit a proposed label to the FDA that does not contain the patented method of using the listed drug." *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359, 1361 (Fed. Cir. 2010); 21 C.F.R. § 314.94(a)(12)(iii)(A). The FDA requires the ANDA applicant to remove the patented use identified in the Section viii Statement from the proposed label. 21 C.F.R. § 314.94(a)(12)(iii)(A); *see Bristol-Myers Squibb Co. v. Shalala*, 91 F.3d 1493, 1499–1500 (D.C. Cir. 1996) (holding that, although the proposed generic drug label should be the same as that of the listed drug, 21 U.S.C. § 355(j)(2)(A)(v) includes an exception that permits the generic label to list fewer than all of the indications recited on the listed drug).

The consequences of filing a Paragraph IV certification versus a Section 505(b)(2)(B) Statement or Section viii Statement are very different. Filing a Paragraph IV certification in connection with a patent claiming a drug product or a use for which the ANDA or Paper NDA applicant seeks approval, is considered an "artificial" act of infringement. Because the applicant cannot market a drug product until it receives FDA approval, Congress enacted Section 271(e)(2)(A) to make filing an ANDA or Paper NDA an act, on paper, of infringement if it contains a "[Paragraph IV] certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990); *see also Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1135 (Fed. Cir. 1995).

Filing a Section 505(b)(2)(B) Statement or Section viii Statement, by contrast, is *not* an act of infringement. *Purepac Pharm. Co. v. Thompson*, 238 F. Supp. 2d 191, 195 (D.D.C. 2002) ("An applicant proceeding by means of a section viii statement . . . does not face an infringement action under 35 U.S.C. § 271(e)(2)(A)."). "[B]ecause an ANDA may not seek approval for an

unapproved or off-label use of a drug under 21 U.S.C. § 355(j)(2)(A)(i), it necessarily follows that 35 U.S.C. 271(e)(2)(A) does not apply to a use patent claiming [an unapproved or off-label use]." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1356 (Fed. Cir. 2003). Thus, the applicant need not inform the patent owner of its application, and the FDA may "approve a section viii application immediately." *Purepac*, 354 F.3d at 880 (citing and quoting *Purepac*, 238 F. Supp. 2d at 195).

2. Judicial Rejection Of Prior Efforts To Deprive ANDA Filers Of Their Right Not To Seek Approval For Methods Of Use Allegedly Covered By A Patent

Plaintiffs are by no means the first brand drug company to ask a court to second guess the Congressional framework establishing Paragraph IV certification as the prerequisite act of infringement. Recently, Novo Nordisk and Eisai made such an attempt in the District of New Jersey. *Novo Nordisk Inc. v. Mylan Pharms. Inc.*, No. CIV. A. 09-2445, 2010 WL 1372437, at *4 (D.N.J. Mar. 31, 2010); *Eisai Co., Ltd. v. Mutual Pharm. Co.*, No. CIV. A. 06-3613, 2007 WL 4556958, at *12 (D.N.J. Dec. 20, 2007).

After extensive analyses of the Hatch-Waxman Act and relevant case law, both the *Novo Nordisk* and *Eisai* courts held that 35 U.S.C. § 271(e)(2) does not create an act of infringement with respect to an ANDA unless the ANDA included a Paragraph IV certification. "[T]o establish an act of infringement pursuant to § 271(e)(2), the ANDA must contain a Paragraph IV certification against a patent listed in the Orange Book for the drug in question." *Eisai*, 2007 WL 4556958, at *12; *Novo Nordisk*, 2010 WL 1372437, at *9-12 (no act of infringement under Section 271(e)(2) with respect to asserted claim of patent for which no Paragraph IV certification filed or required to be filed, even though ANDA applicant had filed Paragraph IV certification as to other unasserted claims of same patent).

Like the plaintiffs in *Novo Nordisk* and *Eisai*, Plaintiffs here interpret Section 271(e)(2)(A) by ignoring the proper context of that section set forth in related provisions of the Hatch-Waxman Act, and disregard the teachings of the Supreme Court and Federal Circuit about the function of Section 271(e)(2)(A) in conjunction with those related provisions. Instead, Plaintiffs rely on a literal interpretation of the subsection's text, which states that "it shall be an act of infringement to submit" an "application under Section 505(j) of the Federal Food, Drug, and Cosmetic Act," (which includes Paper NDAs), requesting approval for a drug "the use of which is claimed in a patent before the expiration of such patent." 35 U.S.C. § 271(e)(2).

The *Eisai* and *Novo Nordisk* courts, however, rejected the same literal construction in light of the statutory context of the Hatch-Waxman Act, and widespread judicial recognition of the significance of a Paragraph IV certification in an ANDA. As observed in *Eisai* and *Novo Nordisk*, the Supreme Court and Federal Circuit have consistently acknowledged that a Paragraph IV certification triggers the act of infringement under Section 271(e)(2) of the Patent Act. *See, e.g., Eli Lilly,* 496 U.S. at 678 ("That is what is achieved by § 271(e)(2)—the creation of a highly artificial act of infringement that consists of submitting an ANDA or a paper NDA containing the fourth type of certification."); *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359, 1362 (Fed. Cir. 2010) ("[T]he [Hatch-Waxman] Act makes a Paragraph IV certification into an act of patent infringement. 35 U.S.C. § 271(e)(2)."); *Bristol-Myers*, 69 F.3d at 1131 ("Inclusion of a paragraph IV certification in an ANDA, however, is deemed an act of infringement.").

As the court in *Novo Nordisk* concluded, "[i]t is clear from the foregoing, that what has driven the conclusion that a Paragraph IV Certification must be filed along with the ANDA to confer jurisdiction over an infringement action under Section 271(e)(2)(A), is what that

Paragraph IV Certification represents [to the brand drug company] for purposes of the infringement action, *i.e.*, that the [Paragraph IV] certification has been filed in error and that infringement would actually occur if the drug were brought to market." *Novo Nordisk*, 2010 WL 1372437, at *10.

D. Plaintiffs' Threadbare Allegation That Watson Should Have Filed A Paragraph IV Certification Cannot Salvage Their Deficient Section 271(e)(2) Claims

Apparently recognizing the deficiencies in their Section 271(e)(2) claims, Plaintiffs included in Counts II and III of the Amended Complaint the unsupported and conclusory allegation that Watson should have filed a Paragraph IV certification with respect to the '618 and '152 patents. (D.I. 48, Am. Compl. ¶¶ 47, 60). This is the type of unsupported allegation the Supreme Court has held incapable of salvaging a deficient claim. *Twombly*, 550 U.S. at 555; *Iqbal*, 129 S. Ct. at 1949. [redacted] Plaintiffs' allegation fails to bring its claims beyond the level of pure speculation, rendering them not ripe for review and insufficient to survive dismissal. *See Novo Nordisk*, 2010 WL 1372437, at *12-13 (dismissing allegation that FDA applicant "should have filed a Paragraph IV certification" as speculation and insufficient to survive a motion to dismiss because there was no allegation that the FDA had actually required the applicant to modify its certification).

IV. CONCLUSION

For the foregoing reasons, Watson respectfully requests that, pursuant to Rule 12(b)(1) and Rule 12(b)(6), the Court dismiss Counts II and III of Plaintiffs' Amended Complaint.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, David E. Moore, hereby certify that on June 16, 2011, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I hereby certify that on June 16, 2011, the attached document was electronically mailed to the following person(s)

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